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TITLE: INFLATION ADAPTOR WITH ALIGNMENT GROOVES

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INFLATION ADAPTOR WITH ALIGNMENT GROOVES

FIELD OF THE INVENTION

[0001] This invention relates generally to balloon catheters and guidewire deployment of catheter-based treatment tools. More specifically, the invention relates to an inflation adaptor with alignment blocks for an occlusion catheter.

BACKGROUND OF THE INVENTION

[0002] One or more treatment catheters may be introduced over and removed from a single guidewire during intravascular treatment procedures such as coronary angioplasty or stent placement. These catheter systems have been developed to facilitate easy and quick exchange of wires and catheters during these medical procedures.

[0003] Guidewires are used conventionally to guide the insertion of various medical instruments such as catheters to a desired treatment location within a patient's vasculature. In a typical procedure, the clinician forms an access point for the guidewire by creating an opening in a peripheral blood vessel, such as the femoral artery. The flexible guidewire is introduced through the opening into the peripheral blood vessel, and advanced by the clinician through the patient's blood vessels until the guidewire extends across the vessel segment to be treated. Various treatment catheters, such as a balloon dilatation catheter for a percutaneous transluminal coronary angioplasty, are inserted over the guidewire and similarly advanced through vasculature until they reach the treatment site.

[0004] The guidewire may be hollow with an inflatable member such as a balloon mounted at its distal end, and an inflation lumen between the inflatable member and an inflation port at its proximal end.

[0005] Hollow guidewires have been designed with low-profile valves that can be opened and closed by detachable inflation adaptors to control the passage of inflation fluid to and from balloons mounted on the guidewires. Such a balloon guidewire is typically connected to a removable inflation manifold or inflation adaptor and includes an integral valve to maintain the balloon in its inflated state when the manifold is removed. A low-profile catheter valve is advantageous for use with occlusion guidewires, as well as therapeutic or anchorable devices that may have outer diameters of 0.014 inches or smaller. Further details regarding catheter valves, catheter balloons, and inflation adaptors are found in "Low Profile Catheter Valve and Inflation Adaptor," Zadno-Azizi et al., U.S. Patent Publication No. 2002/0133117 published September 19, 2002; "Low Profile Catheter Valve and Inflation Adaptor," Zadno-Azizi et al., U.S. Patent 6,325,778; and "Guidewire Inflation System," Zadno-Azizi et al., U.S. Pat. No. 6,050,972, all of which are hereby incorporated by reference in their entirety. Details of various inflation adaptors are found in "Inflation Adaptor and Method of Use," pending U.S. patent publication 10/348,046 filed January 17, 2003, the contents of which are hereby incorporated by reference in their entirety. An integrated inflation/deflation device for delivery of inflation fluid is described in "Integrated Inflation/Deflation Device and Method," Bagaoisan, et al., U.S. Pat. No. 6,234,996, the contents of which are hereby incorporated by reference in their entirety.

[0006] An exemplary inflation adaptor, which may be attached to a low-profile catheter or a hollow guidewire, provides a fluid-tight chamber for introduction of a pressurized fluid that expands a catheter balloon. The inflation chamber releaseably seals its inflation inlet to the inflation port of an elongate, hollow guidewire to form a fluid passage there between. Fluid is supplied to the inflation port under pressure via the fluid passageway. The inflation adaptor also releaseably grips or clamps portions of the hollow guidewire for sliding operation of a valve that controls the flow of inflation fluid to inflate and deflate a catheter balloon. The adaptor may be detached from the hollow guidewire without

deflating the balloon, and the balloon remains inflated until the adaptor is again attached to the catheter, the valve is opened, and the inflation fluid is removed.

[0007] An inflation adapter may include a channel for transversely receiving the guidewire, and clips or guides to help align the guidewire within the channel prior to clamping and sealing the inflation adapter about the hollow guidewire. When a hollow guidewire is transversely inserted in an exemplary adaptor, an inflation port in the guidewire lies within the fluid-tight inflation chamber of the adaptor. The alignment of the flexible, hollow guidewires and small valve stems in the adaptor is critical for a balloon catheter system to work properly. During transverse loading of the flexible hollow guidewire into the inflation adapter, the guidewire may become bent, kinked and/or misaligned with the clamps and seals prior to closing the adapter about the guidewire.

[0008] What is desirable is an improved inflation adaptor that provides faster and easier transverse insertion and alignment of a valve stem and a hollow guidewire into the inflation adaptor. The inflation adaptor should allow for easy transverse loading of a valve stem and a hollow guidewire into the adaptor while avoiding bending or malformation of the valve stem or the hollow guidewire shaft. The inflation adaptor should also provide simple, repeatable positioning of the hollow guidewire within the adapter prior to closing the adapter about the guidewire. A hollow guidewire that is undamaged and correctly positioned within an inflation adapter will provide predictable control of fluid through the hollow guidewire and increased utility and performance of associated medical devices used during the treatment of vascular conditions.

SUMMARY OF THE INVENTION

[0009] One aspect of the invention provides a system for treating a vascular condition including an inflation adaptor having a housing, a clamping device positioned within the housing, and a medial v-groove alignment block. The clamping device includes a jaw and an anvil. A portion of an extended valve stem and a hollow guidewire are received in the medial v-groove alignment block. The extended valve stem and hollow guidewire are engaged by the

clamping device to allow the extended valve stem and the hollow guidewire to be axially translated relative to each other to control a flow of an inflation fluid through the hollow guidewire when the clamping device is in a clamped position.

[00010] Another aspect of the invention is a method of operating an inflation adaptor. The inflation adaptor is positioned to receive a valve stem partially extended from a proximal end of a hollow guidewire to define a first valve configuration. The extended valve stem and the hollow guidewire are inserted into a medial v-groove alignment block. A portion of the extended valve stem and the hollow guidewire are clamped within the inflation adaptor. The valve stem and the hollow guidewire are relatively translated to a second valve configuration to control the flow of an inflation fluid through a portion of the hollow guidewire.

[00011] The present invention is illustrated by the accompanying drawings of various embodiments and the detailed description given below. The drawings should not be taken to limit the invention to the specific embodiments, but are for explanation and understanding. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof. The foregoing aspects and other attendant advantages of the present invention will become more readily appreciated by the detailed description taken in conjunction with the accompanying drawings, which are not to scale.

BRIEF DESCRIPTION OF THE DRAWINGS

[00012] Various embodiments of the present invention are illustrated by the accompanying figures, wherein:

[00013] **FIG. 1** is an illustrative view of a system for treating a vascular condition, in accordance with one embodiment of the current invention;

[00014] **FIG. 2a** is a longitudinal cross-sectional view of a portion of a plug valve in a closed position, in accordance with one embodiment of the current invention;

[00015] **FIG. 2b** is a longitudinal cross-sectional view of a portion of a plug valve in an open position, in accordance with one embodiment of the current invention;

[00016] **FIG. 3** is a perspective view of a medial v-groove alignment block, in accordance with one embodiment of the current invention;

[00017] **FIG. 4** is a perspective view of a distal v-groove alignment block, in accordance with one embodiment of the current invention;

[00018] **FIG. 5** is a perspective view of a proximal v-groove alignment block, in accordance with one embodiment of the current invention;

[00019] **FIG. 6** is an illustrative perspective view of an inflation adaptor including a medial v-groove alignment block, a distal v-groove alignment block and a proximal v-groove alignment block, in accordance with one embodiment of the current invention;

[00020] **FIG. 7** is a perspective view of a jaw for an inflation adaptor, in accordance with one embodiment of the current invention;

[00021] **FIG. 8** is a perspective view of an anvil for an inflation adaptor, in accordance with one embodiment of the current invention;

[00022] **FIG. 9** is an illustrative perspective view of an inflation adaptor including a distal v-groove alignment block, a medial v-groove alignment block, a proximal v-groove alignment block, a jaw and an anvil, in accordance with one embodiment of the current invention;

[00023] **FIG. 10** is a transverse cross-sectional view of a medial v-groove alignment block with a tapered section of a jaw that mates with the medial v-groove alignment block, in accordance with one embodiment of the current invention; and

[00024] **FIG. 11** is a flow diagram of a method for operating an inflation adaptor, in accordance with one embodiment of the current invention.

DETAILED DESCRIPTION OF THE
PRESENTLY PREFERRED EMBODIMENTS

[00025] **FIG.1** illustrates a system for treating a vascular condition, in accordance with one embodiment of the present invention. Vascular condition treatment system **10** includes hollow guidewire **20** having central lumen **22**, valve stem **30**, inflatable balloon **40**, and detachable inflation adaptor **50**, the latter having a medial v-groove alignment block **60** and clamping device **70**. Clamping device **70** including jaw **72** and anvil **74** is positioned within housing **58** of inflation adaptor **50**. Inflatable balloon **40**, which is attached proximate to distal end **26** of hollow guidewire **20**, may be inflated with Inflation fluid **14** from inflation fluid supply **12** that is delivered via central lumen **22** to inflatable balloon **40**, the delivery controlled in part by inflation adaptor **50**.

[00026] For various medical procedures, inflatable balloon **40** comprises, for example, an occlusion balloon, an angioplasty balloon, or a stent-deployment balloon. Vascular condition treatment system **10** may be used, for example, as a temporary occlusion device for blocking fluid flow through arteries or veins. In another medical procedure, vascular condition treatment system **10** is used as a dilatation catheter whereby blood vessels with stenoses may be enlarged by inflating inflatable balloon **40** within the blockage. In other applications, vascular condition treatment system **10** is used in coordination with other treatment catheters, such as a stent-delivery catheter, an aspiration catheter, an inspection catheter, a measurement catheter, an angioplasty catheter, an atherectomy catheter, a drug-delivery catheter, an ultrasound device, a measurement device, a laser catheter, an imaging catheter, a treatment catheter or a therapy catheter. The treatment of vascular conditions may include the prevention or correction of various ailments and deficiencies associated with the cardiovascular system, the cerebrovascular system, and other blood vessels within the body.

[00027] Inflation fluid supply **12** with inflation fluid **14** may be coupled to inflation adaptor **50** with suitable fitting **16**, which connects to inflation fluid supply port **18** of inflation adaptor **50**. Inflation fluid supply port **18** may be a

removable fluid fitting such as a Luer fitting. Inflation fluid **14** may be a saline solution, a radiopaque contrast fluid, a dilute contrast agent, or other suitable liquid that is injectable into inflatable balloon **40**.

[00028] Hollow guidewire **20** is an elongate, flexible tubular member that is inserted into the body to aid in the treatment of various vascular conditions and obstructions in blood vessels such as atherosclerosis, thrombosis and restenosis. Hollow guidewire **20** may be formed, for example, from an extruded or welded tubular material such as nitinol, stainless steel, or other suitable tubing material. In one example, hollow guidewire **20** has an outer diameter of 0.014 inches and an inner diameter on the order of 0.009 inches, with a length between 135 centimeters and 300 centimeters. The length of hollow guidewire **20** may be on the order of 300 centimeters, allowing over-the-wire (OTW) catheters to be inserted into the body once hollow guidewire **20** is in place. In another example, hollow guidewire **20** may be on the order of 175 centimeters in length, suitable for guiding treatment catheters of the rapid-exchange, telescope, multi-exchange and/or zipper types, as are known to those of skill in the art.

[00029] Central lumen **22** within hollow guidewire **20** transports inflation fluid **14** between inflation adaptor **50** and inflatable balloon **40**. Hollow guidewire **20** has proximal end **24** and distal end **26**. Valve port **28**, which is located on a sidewall of hollow guidewire **20** near proximal end **24,** allows inflation fluid **14** to flow to and from attached inflation adaptor **50**, through central lumen **22** of hollow guidewire **20**, and to and from inflatable balloon **40**. Valve port **28** is positioned to fluidly communicate with inflation fluid supply port **18** while a fluid-tight seal contacts the entire circumference of portions of hollow guidewire **20** that are distal to and proximal to valve port **28**. Inflation fluid **14** is injected into interior region **42** of inflatable balloon **40** through balloon inflation hole **44** in a sidewall of hollow guidewire **20**. Balloon inflation hole **44** may include, for example, one or more holes or apertures formed in the sidewall of hollow guidewire **20**, one or more slits in the sidewall, or a spiraling slot cut into the sidewall. At distal end **26** of hollow guidewire **20**, central lumen **22** of hollow guidewire **20** may be plugged or capped to prevent fluid from exiting distal end

26. Additional structures may be added to distal end **26** of hollow guidewire **20**, such as a metallic coil or other flexible tubular element, to assist in guiding hollow guidewire **20** through the body. Radiopaque markers and other indicia for determining the location of inflatable balloon **40** also may be added onto hollow guidewire **20**.

[00030] Valve stem **30** comprises a small diameter, flexible wire slidably received within central lumen **22** of hollow guidewire **20**. Extended portion **32** of valve stem **30** extends outwardly from proximal end **24** of hollow guidewire **20**. Axially received portion **34** of valve stem **30** is positioned within central lumen **22** of hollow guidewire **20** near proximal end **24**. Valve stem **30** comprises, for example, a small-diameter wire of stainless steel, nitinol, or other suitably flexible and strong material. Valve stem **30** may comprise a polymeric material such as nylon or Teflon®, which has good flexibility and sealing properties yet has sufficient rigidity to controllably translate valve stem **30** and valve plug **38** within hollow guidewire **20**. A portion of valve stem **30** received within hollow guidewire **20**, for example, is sinusoidally shaped to provide a desired degree of friction between valve stem **30** and an interior surface of hollow guidewire **20**.

[00031] Exemplary plug valve **36** includes valve plug **38** attached to axially received portion **34** of valve stem **30**. Plug valve **36** may be in an open position or a closed position when valve stem **30** and hollow guidewire **20** are translated relative to each other. The position of valve plug **38** with respect to valve port **28** controls the flow of inflation fluid **14** into and out of inflatable balloon **40**. Valve plug **38** has an interference fit with an interior surface of hollow guidewire **20** to provide a fluid seal. Valve plug **38** is formed from a polymeric material such as polyurethane, an epoxy, a silicone, or a semi-compliant polymer with good sealing and wear-resistant properties. In a first valve configuration, valve plug **38** is positioned distal to valve port **28** of hollow guidewire **20**, and plug valve **36** is in a closed position such that fluid flow is blocked. In a second valve configuration, valve plug **38** is positioned proximal to valve port **28** of hollow guidewire **20**, plug valve **36** is in an open position and fluid flow is allowed

to flow. Extended portion **32** of valve stem **30** and valve plug **38** are translated relative to hollow guidewire **20** to control a flow of inflation fluid **14** into inflatable balloon **40** by blocking or allowing flow through central lumen **22** of hollow guidewire **20**. Pushing valve stem **30** into hollow guidewire **20** past valve port **28** prevents inflation fluid **14** from flowing into or out of inflatable balloon **40**, allowing inflatable balloon **40** to remain inflated when inflation adaptor **50** is removed and other treatment catheters are positioned over hollow guidewire **20** and guided to a treatment location. Re-attaching inflation adaptor **50** and pulling valve stem **30** so that valve plug **38** is positioned proximal to valve port **28** allow fluid in interior region **42** to be removed from inflatable balloon **40**. When inflatable balloon **40** is deflated, valve plug **38** is placed in the closed position to retain some fluid within central lumen **22**, and to avoid air and other gases from entering hollow guidewire **20**.

[00032] To attach inflation adaptor **50**, extended portion **32** of valve stem **30** and a portion of hollow guidewire **20** near proximal end **24** are positioned into v-groove **62** of medial v-groove alignment block **60**. Medial v-groove alignment block **60** is located within housing **58** of inflation adaptor **50** to receive extended portion **32** of valve stem **30** and a portion of hollow guidewire **20**. Extended portion **32** of valve stem **30** may extend past proximal end **54** of inflation adaptor **50** when its placement is complete. As extended portion **32** of valve stem **30** is transversely inserted into inflation adaptor **50**, v-groove **62** of medial v-groove alignment block **60** guides transverse insertion of extended portion **32** of valve stem **30** into medial v-groove alignment block **60**. Tapered section **76** of jaw **72** mates with medial v-groove alignment block **60** and slidably directs extended portion **32** of valve stem **30** into medial v-groove alignment block **60**.

[00033] When extended portion **32** of valve stem **30** is transversely inserted into medial v-groove alignment block **60**, clamping device **70** may be used for engaging valve stem **30** and hollow guidewire **20**. Clamping device **70** is axially aligned with medial v-groove alignment block **60**. Clamping device **70** includes a set of distal pads **80a** and **80b** with frictional surfaces that engage

hollow guidewire **20** distal to valve port **28**, and a set of medial pads **82a** and **82b** with frictional surfaces that engage hollow guidewire **20** proximal to valve port **28** when clamping device **70** is in a clamped position. Distal pads **80a**, **80b**, and medial pads **82a** and **82b** may have teeth, protrusions, texture, or other features to enhance the gripping of hollow guidewire **20**. Clamping device **70** allows valve stem **30** and hollow guidewire **20** to axially move or translate relative to each other when clamping device **70** is in a clamped position, thereby controlling the flow of inflation fluid **14** into inflatable balloon **40**. Clamping device **70** includes a set of sliding pads **84a** and **84b**, as shown in **FIGS. 7** and **8**, with frictional surfaces that engage extended portion **32** of valve stem **30** proximal to proximal end **24** of hollow guidewire **20** and that control axial translation of valve stem **30** relative to hollow guidewire **20**. Sliding pads **84a** and **84b** may have teeth, protrusions, texture, or other features to enhance the gripping of extended portion **32** of valve stem **30**.

[00034] The rotation of multi-position actuation knob **52**, which is coupled to clamping device **70**, allows the axial insertion, engagement, and actuation of plug valve **36**, thereby controlling the flow of inflation fluid **14** into inflatable balloon **40**. In a first position, actuation knob **52** allows extended portion **32** of valve stem **30** and proximal end **24** of hollow guidewire **20** to be transversely inserted into clamping device **70**. In a second position, actuation knob **52** activates clamping device **70** to engage extended portion **32** of valve stem **30** and hollow guidewire **20**. In a third position, actuation knob **52** translates valve stem **30** relative to hollow guidewire **20** to control the flow of inflation fluid **14** into and out from inflatable balloon **40**.

[00035] Inflation fluid **14** from inflation fluid supply **12** that is coupled to inflation adaptor **50** is injected through a portion of hollow guidewire **20** into interior region **42** of inflatable balloon **40** when clamping device **70** is in a clamped position and when plug valve **36** within hollow guidewire **20** is in an open position. Similarly, inflation fluid **14** may be removed from interior region **42** of inflatable balloon **40** when clamping device **70** is in a clamped position and plug valve **36** is in an open position to deflate inflatable balloon **40**.

[00036] Distal v-groove alignment block **90** including v-groove **92** may be located near distal end **56** of inflation adaptor **50** to guide transverse insertion of hollow guidewire **20** into distal v-groove alignment block **90** as hollow guidewire **20** and extended portion **32** of valve stem **30** are transversely inserted into medial v-groove alignment block **60**. Tapered flanks of v-groove **92** slidably direct hollow guidewire **20** into distal v-groove alignment block **90** when hollow guidewire **20** with extended valve stem **30** is transversely inserted into inflation adaptor **50**.

[00037] A proximal v-groove alignment block **94** including v-groove **96** may be located near proximal end **54** of inflation adaptor **50** to guide transverse insertion of extended portion **32** of valve stem **30** into proximal v-groove alignment block **94** as extended portion **32** of valve stem **30** and hollow guidewire **20** are transversely inserted into medial v-groove alignment block **60**. Tapered flanks of v-groove **96** slidably direct extended portion **32** of valve stem **30** into proximal v-groove alignment block **94** when hollow guidewire **20** with extended valve stem **30** is transversely inserted into inflation adaptor **50**.

[00038] **FIG. 2a** shows a longitudinal cross-sectional view of a portion of plug valve **36** in a closed position, in accordance with one embodiment of the present invention. In this figure and following figures, like-numbered elements refer to similar elements as in **FIG. 1**. Plug valve **36** includes extended portion **32** of valve stem **30** extending outwardly from proximal end **24** of hollow guidewire **20**. Axially received portion **34** of valve stem **30** extends into a portion of central lumen **22** near proximal end **24** of hollow guidewire **20**. Plug valve **36** is positioned in one of an open position or a closed position to control the flow of inflation fluid in central lumen **22** of hollow guidewire **20**. Axially translating valve stem **30** of plug valve **36** controls flow of inflation fluid through central lumen **22** of hollow guidewire **20**. Valve plug **38** is attached near a distal end of valve stem **30**. Valve plug **38** allows inflation fluid to flow in and out of central lumen **22** of hollow guidewire **20**. When valve stem **30** is translated within hollow guidewire **20** relative to valve port **28** formed in a sidewall of hollow guidewire **20**, plug valve **36** may be opened and closed, allowing fluid such as inflation fluid to be

injected into and withdrawn from central lumen **22** to and from a distal end of hollow guidewire **20**. When plug valve **36** is closed as shown, the flow of inflation fluid is blocked, for example, to prevent air or liquid from flowing through central lumen **22** or to keep an occlusion balloon inflated while in the body. When valve plug **38** is positioned across or distal to valve port **28**, plug valve **36** is closed. When valve plug **38** is positioned proximal to valve port **28** as shown in **FIG. 2b**, plug valve **36** is open and fluid may flow through valve port **28** and central lumen **22** to and from a distal end of hollow guidewire **20**.

[00039] **FIG. 2b** shows a longitudinal cross-sectional view of plug valve **36** of **FIG. 2a** in an open position, in accordance with one embodiment of the present invention. As valve stem **30** is translated to axially move valve plug **38** to a position proximal to valve port **28** and to open plug valve **36**, inflation fluid **14** may be injected through valve port **28** and into central lumen **22** of hollow guidewire **20**. Similarly, inflation fluid **14** may be withdrawn from central lumen **22** of hollow guidewire **20** through open valve port **28**.

[00040] **FIG. 3** shows a perspective view of medial v-groove alignment block **60**, including v-groove **62** formed on one side thereof. V-groove **62** guides a transverse insertion of extended portion **32** of valve stem **30** into medial v-groove alignment block **60**. Flanks of v-groove **62** slidably direct extended portion **32** of valve stem **30** into medial v-groove alignment block **60**. Medial v-groove alignment block **60** may include slot **64** that extends from the apex of v-groove **62** to accommodate hollow guidewire **20** and valve stem **30**. Slot **64**, when used, is appropriately sized to allow the ready transverse insertion of extended valve stem **30** and a portion of hollow guidewire **20** into slot **64** to maintain hollow guidewire **20** in a position suitable for clamping. Medial v-groove alignment block **60** has a central recess to mate with tapered section **76** of jaw **72**, illustrated in **FIG. 10**. The central recess eliminates material in medial v-groove alignment block **60** such that there is effectively a relatively short v-groove **62** at each end, with an optional slot **64** associated with each v-groove **62**. One example of medial v-groove alignment block **60** has a height of 0.625 inches, a width of 0.252 inches, a length of 0.500 inches, a v-groove flank angle

of 30 degrees, a slot width of 0.0189 inches, and a slot depth of 0.100 inches. The flanks of v-groove **62** and the v-grooves of other alignment blocks may be symmetrically configured about a center axis and having an included taper angle, for example, of 60 degrees. Alternatively, the flanks of v-groove **62** and other alignment blocks may be asymmetric about a center axis and having, for example, one flank at an angle and an opposing flank without any slanting or taper such as 45 degrees and 0 degrees, respectively.

[00041] **FIG. 4** shows a perspective view of a component of an inflation adaptor including a distal v-groove alignment block, in accordance with one embodiment of the present invention. Distal v-groove alignment block **90** includes v-groove **92** formed on one side of distal v-groove alignment block **90**. V-groove **92** guides a transverse insertion of hollow guidewire **20** into distal v-groove alignment block **90**. Flanks of v-groove **92** slidably direct a portion of hollow guidewire **20** into distal v-groove alignment block **90**. Distal v-groove alignment block **90** may be slotted to accommodate hollow guidewire **20**. The slot, when used, is appropriately sized to allow the ready transverse insertion of a portion of hollow guidewire **20** into the slot to maintain hollow guidewire **20** in a position suitable for clamping. One example of distal v-groove alignment block **90** has a length of nominally 0.400 inches with taper angles and slot dimensions that match the medial v-groove alignment block.

[00042] **FIG. 5** shows a perspective view of a component of an inflation adaptor including a proximal v-groove alignment block, in accordance with one embodiment of the present invention. Proximal v-groove alignment block **94** includes v-groove **96** formed on one side of proximal v-groove alignment block **94**. V-groove **96** guides a transverse insertion of extended portion **32** of valve stem **30** into proximal v-groove alignment block **94**. Flanks of v-groove **96** slidably direct a portion of extended valve stem **30** into proximal v-groove alignment block **94**. Proximal v-groove alignment block **94** may be slotted to accommodate extended portion **32** of valve stem **30**. The slot, when used, is appropriately sized to allow the ready transverse insertion of a portion of valve stem **30** into the slot to maintain valve stem **30** in a position suitable for clamping.

One example of proximal v-groove alignment block **94** has a length of nominally 0.300 inches with taper angles and slot dimensions that match the medial v-groove alignment block.

[00043] **FIG. 6** shows an illustrative perspective view of an inflation adaptor including medial v-groove alignment block **60**, distal v-groove alignment block **90**, and proximal v-groove alignment block **94**, in accordance with one embodiment of the present invention. Medial v-groove alignment block **60** is attached to or formed integrally with housing **58** of inflation adaptor **50**. Alternatively, medial v-groove alignment block **60** may be attached to anvil **74**. Medial v-groove alignment block **60** may include slot **64** that extends from the apex of v-groove **62** to accommodate hollow guidewire **20** and valve stem **30**. Distal v-groove alignment block **90** with v-groove **92** is attached to or formed integrally with housing **58** near distal end **56** of inflation adaptor **50**. Distal v-groove alignment block **90** is axially aligned with medial v-groove alignment block **60** to receive hollow guidewire **20**. Proximal v-groove alignment block **94** with v-groove **96** is attached to or formed integrally with housing **58** near proximal end **54** of inflation adaptor **50**. Proximal v-groove alignment block **94** is axially aligned with medial v-groove alignment block **60** to receive extended portion **32** of valve stem **30**. Medial v-groove alignment block **60**, distal v-groove alignment block **90**, and proximal v-groove alignment block **94** are axially aligned and positioned within housing **58** of inflation adaptor **50** to allow hollow guidewire **20** and valve stem **30** to be positioned within inflation adaptor **50**.

[00044] **FIG. 7** shows a perspective view of jaw **72** for an inflation adaptor, in accordance with one embodiment of the present invention. Jaw **72** includes planar surface **68** with recesses for distal pad **80a** and medial pad **82a**. Jaw **72** includes an opening for sliding pad **84a**. Jaw **72** is slotted on each side of tapered section **76** to accommodate a medial v-groove alignment block. Planar surface **68** may additionally include teeth, trapezoidal protrusions or other features for valve stem and hollow guidewire insertion.

[00045] **FIG. 8** shows a perspective view of anvil **74** for an inflation adaptor, in accordance with one embodiment of the present invention. Anvil **74**

is adapted with a cutout region to receive a medial v-groove alignment block, and contains recesses for distal pad **80b** and medial pad **82b**. Anvil **74** includes an opening for sliding pad **84b**. Anvil **74** may include elongated longitudinally oriented channel **78** to accommodate a hollow guidewire with an extended valve stem.

[00046] **FIG. 9** shows an illustrative perspective view of inflation adaptor **50** including housing **58**, medial v-groove alignment block **60**, distal v-groove alignment block **90**, proximal v-groove alignment block **94**, jaw **72** and anvil **74**, in accordance with one embodiment of the present invention. Inflation adaptor **50** includes medial v-groove alignment block **60** (not shown for sake of clarity) attached to housing **58** of inflation adaptor **50**. Alternatively, medial v-groove alignment block **60** may be attached to anvil **74**. Distal v-groove alignment block **90** is attached to or formed integrally with housing **58**. Proximal v-groove alignment block **94** is attached to or formed integrally with housing **58**. Jaw **72** and anvil **74** are positioned within inflation adaptor **50** to allow transverse insertion of hollow guidewire **20** with valve stem **30** into inflation adaptor **50**. Extended portion **32** of valve stem **30** and hollow guidewire **20** are received in medial v-groove alignment block **60**, distal v-groove alignment block **90** and proximal v-groove alignment block **94**, and are engaged by a clamping device, including jaw **72** and anvil **74**, for controlling flow of inflation fluid through a portion of hollow guidewire **20**.

[00047] **FIG. 10** shows a side view of medial v-groove alignment block **60** and tapered section **76** of jaw **72**, in accordance with one embodiment of the present invention. Tapered section **76** of jaw **72** mates with medial v-groove alignment block **60**. Tapered section **76** is moved into a recessed region of medial v-groove alignment block **60** to clamp hollow guidewire **20** with valve stem **30**. As tapered section **76** of jaw **72** moves into medial v-groove alignment block **60**, tapered section **76** slidably directs hollow guidewire **20** and valve stem **30** along flanks of v-groove **62** into slot **64**. Channel **78** of tapered section **76** is positioned to contain extended portion **32** of valve stem **30** and hollow guidewire

20 when extended portion **32** of valve stem **30** and hollow guidewire **20** are positioned in medial v-groove alignment block **60**.

[00048] **FIG. 11** shows a flow diagram of a method for operating an inflation adaptor, in accordance with one embodiment of the present invention. This method includes various steps to operate an inflation adaptor with a medial v-groove alignment block. The description pertains to the inflation and deflation of an inflatable balloon attached near the distal end of a balloon catheter, such as an occlusion catheter. Alternatively, the inflation adaptor operation method may be used to inflate and deflate an angioplasty balloon or to deploy a stent coupled to a stent-deployment balloon. Vascular condition treatment methods employing the inflation adaptor provide, for example, one or more vascular treatments for the prevention or correction of various ailments and deficiencies including those associated with the cardiovascular system, the cerebrovascular system, and other blood vessels within the body.

[00049] A balloon catheter with a hollow guidewire and an inflatable balloon is inserted and positioned in a bodily vessel, as seen at block **102**. The hollow guidewire with the inflatable balloon near its distal end is manipulated manually through the vascular system to the desired location for placement of the balloon. For example, a needle puncture is made in the body near the femoral artery, and the hollow guidewire with the inflatable balloon is inserted through the puncture, through the femoral artery, and into a position within a blood vessel where the balloon may be inflated to block fluid flow in the vessel. A central lumen within the hollow guidewire and other lumens may be purged with inflation fluid such as diluted contrast fluid or saline solution before the balloon catheter is inserted into the body. Prior to the positioning of the balloon catheter, fluoroscopic contrast fluid may be injected into the blood vessel in order to identify, visualize and verify the location of a stenosis, blockage, or other medical condition within the blood vessel. In one example, the hollow guidewire and the inflatable balloon are advanced through a vessel and positioned distal to the site of a stenosis.

[00050] When the balloon and the hollow guidewire have been appropriately positioned, the inflation adaptor is positioned to receive a valve stem partially extended from a proximal end of the hollow guidewire to define a first valve configuration, such as a closed position. A portion of the valve stem with an attached valve plug extends into a proximal portion of the hollow guidewire, forming a plug valve that controls the flow of fluid through a valve port in a sidewall of the hollow guidewire and into the inflatable balloon near the distal end of the hollow guidewire.

[00051] To attach the inflation adaptor to the balloon catheter, the extended valve stem is transversely inserted and positioned into one or more alignment blocks having v-grooves, as seen at block **104**. One embodiment of the present invention has a medial v-groove alignment block, a distal v-groove alignment block and a proximal v-groove alignment block. The extended portion of the valve stem and the proximal end of the hollow guidewire are transversely inserted into a v-groove of the medial v-groove alignment block as the hollow guidewire is transversely inserted into a v-groove of the distal v-groove alignment block and the extended portion of the valve stem is transversely inserted into a v-groove of the proximal v-groove alignment block.

[00052] In another embodiment of the present invention, which has neither the distal v-groove alignment block nor the proximal v-groove alignment block, the extended valve stem and the hollow guidewire are transversely inserted and positioned into the v-groove of the medial v-groove alignment block and into the medial v-groove alignment block. Another embodiment of the present invention employs a distal v-groove alignment block in conjunction with the medial v-groove alignment block. In yet another embodiment, a proximal v-groove alignment block is used in conjunction with the medial v-groove alignment block. In all aforementioned embodiments of the present invention, the valve port in the hollow guidewire is appropriately positioned and aligned with an inflation fluid supply port within the inflation adaptor using, for example, metallic or colored markers, indicia, or other suitable indicators for the valve port.

[00053] A portion of the extended valve stem and the hollow guidewire are clamped, as seen at block **106**. The valve stem and the hollow guidewire are axially translated with respect to each other to a second valve configuration to control flow of inflation fluid through a portion of the hollow guidewire. For example, a clamping device within the inflation adaptor is actuated by rotating an actuation knob from a first position that allows the transverse insertion of the extended valve stem and hollow guidewire to a second position that activates a clamping device to engage the extended valve stem and the hollow guidewire. Clamping the extended portion of the valve stem and the hollow guidewire comprises, for example, engaging the hollow guidewire with a set of distal pads and a set of proximal pads, and engaging the extended valve stem with a set of sliding pads. When the valve stem and the hollow guidewire are clamped, seals around the valve port in the hollow guidewire are secured, allowing pressurized fluid from an inflation fluid supply to be injected into the valve port and through the hollow guidewire.

[00054] At this point in the method, an inflation fluid supply is coupled to the inflation adaptor. Inflation fluid such as dilute contrast agent or other suitable fluid may be contained in an inflation device and connected to an inflation fluid port on the inflation adaptor, such as a Luer fitting. Various standard procedures can be used to remove air and other gases from the inflation device, inflation fluid lines connected to the inflation adaptor, and chambers within the inflation adaptor. Alternatively, the inflation fluid supply may be connected to the inflation adaptor prior to attaching the inflation adaptor to the balloon catheter, prior to inserting the hollow guidewire into the body, or at other times during treatment, depending on the preference of the medical practitioner.

[00055] The valve stem is translated relative to the hollow guide wire when in the clamped position. Flow of an inflation fluid through a portion of the hollow guidewire is controlled based on the relative translation. For example, a plug valve, which includes a polymeric valve plug attached near a distal end of a portion of the valve stem that extends into the hollow guidewire, is operated by axially displacing the valve stem with respect to the hollow guidewire. Axial

translations of the valve stem relative to the hollow guidewire block allow the flow of inflation fluid through a valve port in the side of the hollow guidewire. When in a closed position, the valve plug is located distal to the valve port and prevents the flow of fluid through a guidewire central lumen. When in an open position, the valve plug is located proximal to the valve port, allowing fluid to flow through a portion of the hollow guidewire and into or out from an inflatable balloon near the distal end of the hollow guidewire. The plug valve may be opened, for example, by rotating an actuation knob of the inflation actuator from the second position to a third position, which translates the valve stem with respect to the valve stem to an open valve position.

[00056] The inflatable balloon proximate to a distal end of the hollow guidewire is inflated, as seen at block **108**. The inflatable balloon is inflated by forcing inflation fluid from the inflation fluid supply through a fluid supply port in the inflatable adaptor, through the valve port in the sidewall of the hollow guidewire, through the guidewire central lumen, through one or more balloon inflation holes of the inflatable balloon, and into an interior region of the inflatable balloon. The inflatable balloon is inflated with the injected inflation fluid to the desired size, which may be monitored with injections of radiopaque contrast fluid and/or with associated x-ray imaging systems. Following the inflation of the balloon, an angiogram using fluoroscopy may be taken to ensure the complete occlusion of a vessel by the balloon.

[00057] When the inflatable balloon is inflated to the desired diameter and is occlusively apposed or anchored to the vessel wall, the valve stem within the hollow guidewire is axially translated to close the plug valve, as seen at block **110**. Translation of the valve stem within the hollow guidewire is achieved, for example, by rotating the actuation knob from the third position back to the second position.

[00058] Inflation fluid within the inflatable balloon is retained to keep the inflatable balloon inflated and the inflation adaptor is detached, as seen at block **112**. The inflation adaptor is detached by unclamping the valve stem and hollow guidewire, and then sliding and removing the inflation adaptor from the

valve stem and hollow guidewire. The valve stem and hollow guidewire are unclamped, for example, by rotating the actuation knob from the second position back to the first position.

[00059] When the inflation adaptor is detached, one or more treatments may be applied to the vessel, as seen at block **114**. In one treatment example, a balloon dilation catheter may be advanced over the hollow guidewire to the treatment site where angioplasty is performed. After the restriction has been treated, the primary treatment catheter may be removed from over the hollow guidewire and then an aspiration catheter can be advanced to the treatment site to aspirate any embolic debris generated during the angioplasty. Other types of catheters such as imaging catheters, over-the-wire treatment catheters, rapid exchange catheters, stent deployment catheters, inspection catheters or other types of catheters may be used in conjunction with the hollow guidewire.

[00060] When one or more treatments have been completed, the inflation adaptor is reattached. The hollow guidewire with the extended valve stem is transversely inserted through the receiver(s) of the one or more alignment blocks within the inflation adaptor. After being properly aligned within the inflation adaptor, the hollow guidewire and the extended valve stem are clamped. Once clamped, the extended valve stem is again translated with respect to the hollow guidewire to slide the valve plug past the valve port and open the valve.

[00061] The inflatable balloon is deflated, as seen at block **116**. The balloon may be deflated when inflation fluid within the inflatable balloon is drawn out or when it is forced out, for example, by elastic restoring forces exerted on the inflation fluid within the interior region by the balloon material. The inflatable balloon may be deflated, for example, with an inflation/deflation device coupled to the inflation adaptor.

[00062] The inflation adaptor may be detached prior to removal of the hollow guidewire, as seen at block **118**. Once the inflatable balloon is deflated, the plug valve is axially translated into a closed position. The inflation

fluid supply may be disconnected from the inflation fluid supply port on the inflation adaptor. The hollow guidewire and the valve stem are unclamped, and the inflation adaptor is readily removed. The balloon catheter with the hollow guidewire and the inflatable balloon may be repositioned within the body or removed from the body and discarded. When the inflation adapter is used to inflate and deflate the balloon of an angioplasty or stent delivery catheter, steps **110** through **114** are omitted.

[00063] In addition to the inflation adaptor being used in treatments employing occlusion balloon catheters, angioplasty catheters, balloon dilatation catheters and stent-deployment catheters, it also may be used in other applications such as the deployment of emboli filters and other procedures utilizing controlled axial translations of a wire within a small-diameter hollow tube.

[00064] Variations and alterations in the design, manufacture and methods of use of the inflation adaptor are apparent to one skilled in the art, and may be made without departing from the spirit and scope of the present invention. While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.